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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,118	09/03/2003	Tim A. Fischell	CRD-5047	4013

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EXAMINER	
AUGHENBAUGH, WALTER	
ART UNIT	**PAPER NUMBER**
1772	

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/654,118	FISCHELL ET AL.	
	Examiner	Art Unit	
	Walter B. Aughenbaugh	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because it is over 150 words long and because it is directed to a method of using a stent delivery system rather than the claimed subject matter, which is the stent itself. Correction is required. See MPEP § 608.01(b).

Claim Objections

4. Claim 1 is objected to because of the following informalities: the recitation "the stent being in the form of a longitudinal axis, a proximal end and a distal end" is contrary to the standard meanings of the terms used in this recitation (e.g. how can a stent be "in the form of" an axis?). Examiner suggests incorporating the language of claim 10 into claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Vrba.

In regard to claim 1, Vrba teaches a stent for implantation into a vessel of a human body (col. 2, lines 6-11) comprising a longitudinal axis, a proximal end and a distal end (Fig. 1). Vrba teaches that the stent has a distal section (item 14, Fig. 1) comprising a plurality of circumferential sets of strut members where each set of strut members are longitudinally separated from each other and each set of strut members form a cylindrical portion of the stent (col. 2, lines 6-20 and Fig.1). Vrba teaches that the stent has a proximal section (item 12, Fig. 1) comprising more than three spokes (where item 12 of Fig. 1 consists of spokes, or where the five

connecting elements between item 12 and item 14 as shown in Fig. 1 correspond to spokes) where each spoke is connected to the proximal-most circumferential set of strut members of the distal section of the stent (col. 2, lines 9-11 and Fig. 1).

In regard to claim 2, Vrba teaches that the stent is self-expanding (col. 2, lines 6-11). In regard to claim 3, Vrba teaches that the stent is balloon expandable (col. 2, lines 6-7). In regard to claim 4, Vrba teaches that each spoke is only attached to the proximal-most circumferential set of strut members of the distal section of the stent, as opposed to the spokes being attached to any of the circumferential set of strut members other than the proximal-most circumferential set of strut members of the distal section of the stent (Fig. 1).

In regard to claim 5, Vrba teaches that each spoke is connected to adjacent spokes by strut members where the strut members collectively form a circumferential set of strut members at the proximal end of the stent in item 12 of Fig. 1. In regard to claim 6, Vrba teaches that each circumferential set of strut members comprises a plurality of connected curved sections (Fig. 1) and that the number of spokes (in item 12 of Fig. 1) is equal to the number of curved sections in the proximal-most circumferential set of strut members of the distal section (item 14, Fig. 1) of the stent where each pair of consecutive horizontal portions of item 12 corresponds to a spoke (see Fig. 1). In regard to claim 7, Vrba teaches that each circumferential set of strut members comprises a multiplicity of connected curved sections (Fig. 1) and that the number of spokes (between item 12 and item 14 of Fig. 1) is less than the number of curved sections in the proximal-most circumferential set of strut members of the distal section (item 14, Fig. 1) of the stent (see Fig. 1). In regard to claim 8, Vrba teaches that each circumferential set of strut members comprises a multiplicity of connected curved sections (Fig. 1) and that the number of

spokes (in item 12 of Fig. 1) is more than the number of curved sections in the proximal-most circumferential set of strut members of the distal section (item 14, Fig. 1) of the stent where each horizontal portion of item 12 corresponds to a spoke (see Fig. 1).

7. Claims 10-13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Lam.

Lam teaches a stent for implantation into a vessel of a human body (col. 2, lines 11-15) comprising a longitudinal axis, a proximal end and a distal end (Fig. 2 and 3). Lam teaches that the stent has a cylindrical distal section (tubular body, item 24, Fig. 2 and 3) and a split proximal section (flaring portion, item 25, Fig. 2 and 3) designed to be flared outward with respect to the cylindrical distal section (col. 5, lines 51-48 and col. 6, lines 7-15).

In regard to claim 11, Lam teaches that a portion of the split proximal section (flaring portion, item 25, Fig. 2 and 3) includes a radiopaque material (radiopaque markers, item 35, Fig. 2 and 3, which enhances the radiopacity of the split proximal section, col. 6, lines 16-28). In regard to claim 12, Lam teaches that the radiopaque markers, item 35, are attached to the exterior surface of some portion of the split proximal section (flaring portion, item 25), and that the location of the radiopaque markers is selected to facilitate placement of the stent within a vessel (col. 6, lines 16-22); therefore, the condition where the radiopaque material is coated onto the exterior surface of some portion of the split proximal section falls within the scope of Lam.

In regard to claim 13, Lam teaches that the radiopaque material (radiopaque markers, item 35) is inserted into one or more holes in the split proximal section because Lam teaches that the radiopaque markers, item 35, are formed in the pedals, item 27, of the split proximal section (flaring portion, item 25, col. 6, lines 16-17 and Fig. 3).

In regard to claim 15, Lam teaches that the split proximal section (flaring portion, item 25) comprises individual spokes (pedals, item 27) with each spoke having a radiopaque insert, item 35 (col. 6, lines 16-22 and Fig. 3).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lam.

Lam teaches the stent as discussed above. In regard to claims 16 and 17, Lam teaches that the split proximal section (flaring portion, item 25) comprises individual spokes (pedals, item 27) with each spoke having a radiopaque insert, item 35 (col. 6, lines 16-22 and Fig. 3). Lam fails to explicitly teach that the every other spoke has a radiopaque insert as claimed in claim 16 or that less than half of the spokes have a radiopaque insert as claimed in claim 17. Lam, however, teaches that radiopaque markers are used to mark the location of a stent within a vessel so that the stent can be precisely positioned within the vessel (col. 3, lines 34-41). Therefore, one of

ordinary skill in the art would have recognized to have inserted a radiopaque marker in every other spoke or less than half of the spokes of the stent of Lam such that the radiopaque markers are positioned such that the location of the stent within a vessel can be ascertained in order to precisely position the stent within the vessel as taught by Lam.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have inserted a radiopaque marker in every other spoke or less than half of the spokes of the stent of Lam such that the radiopaque markers are positioned such that the location of the stent within a vessel can be ascertained in order to precisely position the stent within the vessel as taught by Lam.

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vrba in view of Lam.

Vrba teaches the stent as discussed above. Vrba fails to teach that the stent comprises three radiopaque markers. Lam, however, teaches that radiopaque markers are used to mark the location of a stent within a vessel so that the stent can be precisely positioned within the vessel (col. 3, lines 34-41). Therefore, one of ordinary skill in the art would have recognized to have added three radiopaque markers to the stent of Vrba (thus forming the claimed "stent delivery system") that are situated such that the markers can be used to mark the location of a stent within a vessel in order to precisely position the stent within the vessel as taught by Lam.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added three radiopaque markers to the stent of Vrba that are situated such that the markers can be used to mark the location of a stent within a vessel in order to precisely position the stent within the vessel as taught by Lam.

11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lam in view of Shaknovich.

Lam teaches the stent as discussed above. Lam fails to explicitly teach that the radiopaque material includes any of the claimed materials. Shaknovich, however, discloses that gold, tantalum and platinum are well known materials for use as radiopaque markers for stents (col. 12, lines 41-43). Therefore, one of ordinary skill in the art would have recognized to have used gold, tantalum or platinum as the material of the radiopaque markers of the stent of Lam since gold, tantalum and platinum are well known materials for use as radiopaque markers for stents as taught by Shaknovich.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used gold, tantalum or platinum as the material of the radiopaque markers of the stent of Lam since gold, tantalum and platinum are well known materials for use as radiopaque markers for stents as taught by Shaknovich.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 6:00pm and on alternate Fridays from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh
09/30/05 WBA

HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

9/30/05